

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Klaus Rudolf) Art Unit: 1625
Serial No. : 10/687,262) Examiner: CHANG, CELIA C
Filed : 10-16-2003
Confirmation No. : 9943
Title : SELECTED CGRP ANTAGONISTS, PROCESSES FOR
PREPARING THEM AND THEIR USE AS PHARMACEUTICAL
COMPOSITIONS
Patent No. : 7,595,312
Issued : 09-29-2009
Docket No. : 01-1402

APPLICATION FOR PATENT TERM ADJUSTMENT

Via EFS Web
Mail Stop: Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a request for reconsideration of the PTA indicated on the face page of US 7,595,312. The USPTO states that the PTA is 203 days. Applicants submit that the PTA should be 635 days. This application for patent term adjustment pursuant to 37 C.F.R. § 1.705(d) is being filed within two months of the patent issue date (i.e., 29 September 2009), and therefore this request is timely filed under 37 C.F.R. § 1.705(d).

Pursuant to 37 C.F.R. § 1.705(b)(1) the required fee of \$200.00 set forth in 37 C.F.R. § 1.18(e) is being paid herewith, via the USPTO's electronic filing system (by authorization to charge such fee to Applicant's Deposit Account No. 02-2955).

Pursuant to 37 C.F.R. § 1.705(b)(2)(i), below is an indication of the correct patent term adjustment and the basis or bases under § 1.702 for the adjustment:

Correct Patent Term Adjustment (PTA) =635 days

Bases for the above PTA

Additions

(A) 432 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1);
plus
(B) 561 days under 37 C.F.R. §§ 1.702(b) and 1.703(b).

Subtractions

(C) 358 days under 37 C.F.R. § 1.704(b);

Total PTA = ((A) 432 days + (B) 561 days) - (C) 358 days = 635 days

Pursuant to 37 C.F.R. § 1.705(b)(2)(ii), below is an indication of the relevant dates specified in 37 C.F.R. § 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703 (f) to which the patent is entitled:

(A) 432 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1)

The 432 days under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1) is calculated based on the following dates:

(1) The day after the date that is 14 months after the date on which the application was filed under 35 U.S.C. 111(a) = 17 December 2004

(2) The date of mailing of the first action under 35 U.S.C. 132 = 21 February 2006

(3) The number of days beginning on 17 December 2004 and ending on 21 February 2006 = 432 days

(B) 561 days under 37 C.F.R. §§ 1.702(b) and 1.703(b)

The 561 days under 37 C.F.R. §§ 1.702(b) and 1.703(b) is calculated based on the following dates:

(1) The day *after* the date that is 3 years after the date on which the application was filed under 35 U.S.C. 111(a) = 17 October 2006

(2) The filing of a Request for Continued Examination (RCE) = 29 April 2008

(3) The number of days beginning on 17 October 2006 and ending on 29 April 2008 = 561days

The PTA specified in 37 C.F.R. § 1.703(f) to which the patent is entitled

As specified in 37 C.F.R. § 1.703(f), the term of a patent entitled to adjustment under §1.702 and § 1.703 shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of § 1.703, to the extent such periods are not overlapping, less the sum of the periods calculated under § 1.704.

For US 7,595,312 the sum of the periods under paragraphs (a) through (e) of § 1.703 is 993 days, calculated as follows:

(A) 432 days delay under 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1);

plus

(B) 561 days delay under 37 C.F.R. §§ 1.702(b) and 1.703(b);

The two periods of delay specified above are not overlapping, since the first period of delay under 37 C.F.R. §1.703(a)(1) ended on 21 February 2006 (when the first office action was mailed) and the second period of delay under 37 C.F.R. §1.703(b) did not start until 17 October 2006 (the day after the date that is 3 years after the date on which the application was filed). The PAIR system Patent Term Adjustment page indicates a 129 day PTO delay for PTA 36 month adjustment. However, Applicants see no basis for the 129 day adjustment

since there were no days falling within both periods of delay and therefore no overlap¹.

For US 7,595,312 the sum of the periods calculated under 37 C.F.R. § 1.704 is 358 days, as follows:

(C) 358 days under 37 C.F.R. § 1.704(b)

An Office Action was issued on 21 February 2006, to which a response was not filed until 31 May 2006, which was 10 days beyond the 3 month period specified in § 1.704(b) - thus, a 10 day reduction.

An Office Action was issued on 28 June 2006, to which a response was not filed until 21 December 2006, which was 84 days beyond the 3 month period specified in § 1.704(b) - thus, an 84 day reduction.

An Office Action was issued on 27 February 2007, to which a response was not filed until 17 August 2007, which was 82 days beyond the 3 month period specified in § 1.704(b) - thus, an 82 day reduction.

An Office Action was issued on 29 October 2007, to which an RCE was not filed until 29 April 2008, which was 91 days beyond the 3 month period specified in § 1.704(b) - thus, a 91 day reduction.

An Office Action was issued on 28 July 2008, to which a response was not filed until 27 January 2009, which was 91 days beyond the 3 month period specified in § 1.704(b) - thus, a 91 day reduction.

Therefore, the PTA specified in 37 C.F.R. § 1.703(f) to which the patent is entitled is 635 days, calculated as follows:

993 days (the sum of the periods under paragraphs (a) through (e) of § 1.703)
minus

358 days (the sum of the periods calculated under § 1.704)
=635 days

¹ See Wyeth v. Dudas, 580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008)

With respect to 37 C.F.R. § 1.705(b)(2)(iii), US 7,595,312 is not subject to a terminal disclaimer since no such disclaimer was filed.

With respect to 37 C.F.R. § 1.705(b)(2)(iv), there were circumstances during prosecution of US 7,595,312 constituting failure to engage in reasonable efforts to conclude processing or examination of the application under 37 C.F.R. § 1.704. These circumstances are as outlined above under (C) resulting in the following PTA reductions: 358 days under 37 C.F.R. § 1.704(b) [for responses filed 31 May 2006, 21 December 2006, 17 August 2007, 29 May 2008 and 27 January 2009] for a total of PTA reduction of 358 days.

Accordingly, Applicants respectfully request that the PTA indicated on the face page of the US 7,595,312 Patent (stated therein to be 203 days) be corrected to 635 days for the reasons as outlined above.

The Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 02-2955.

Respectfully submitted,

/Alan Stempel/

Alan Stempel, Registration # 28,991
Attorney for Applicant(s)

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road, P.O. Box 368
Ridgefield, CT 06877
Tel: 203-798-4868
Attorney Docket No. 01-1402
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